

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

GREGORY KLINE and CHERRIE KLINE,)	
Plaintiffs,)	
)	
vs.)	Civil Action No. 13-513
)	Judge Conti
ZIMMER HOLDINGS, INC., ZIMMER, INC.)	Magistrate Judge Mitchell
and ZIMMER US, INC.,)	
Defendants.)	

REPORT AND RECOMMENDATION

I. Recommendation

It is respectfully recommended that the amended motion for summary judgment filed on behalf of the defendants (ECF No. 70) be granted. It is further recommended that the amended motion in limine to exclude specific opinions of plaintiffs' expert witnesses filed on behalf of the defendants (ECF No. 74) be dismissed as moot. It is further recommended that the motion to strike the affidavits of Mari Truman and Nicholas Sotereanos, M.D. filed on behalf of the defendants (ECF No. 84) be denied.

II. Report

Plaintiffs, Gregory Kline and his wife Cherrie Kline, filed this action alleging claims of negligence, strict liability, breach of express warranties, breach of implied warranties and loss of consortium under Pennsylvania law, arising out of injuries sustained by Gregory Kline from an allegedly defective hip replacement component manufactured by Defendants, Zimmer Holdings, Inc., and/or its wholly-owned subsidiaries, Zimmer, Inc. and Zimmer US, Inc. (together, "Zimmer"). As a result of an order entered on June 27, 2013 (ECF No. 23) with respect to Defendants' motion to dismiss and based upon Plaintiffs' response to the pending amended motion for summary judgment, the only claims remaining in the case are Gregory Kline's claims for negligence based on a design defect and a warnings defect and Cherrie's Kline's claim for

loss of consortium.

Presently pending before the Court are three motions filed by Defendants: an amended motion for summary judgment, an amended motion in limine to exclude specific opinions of Plaintiffs' expert witnesses and a motion to strike the affidavits of Mari Truman and Nicholas Sotereanos, M.D.¹ For the reasons that follow, the motion to strike should be denied, the motion for summary judgment should be granted and the motion in limine should be dismissed as moot.

Facts

Plaintiff Gregory Kline is a 54-year-old male with a history of horrific degenerative joint disease in his right hip. (Kline Dep. at 6:16-20;² Sotereanos Dep. at 16:17-24.³) On January 13, 2010, Mr. Kline underwent a total right hip replacement surgery, which was performed by Dr. Nicholas Sotereanos. (Sotereanos Dep. at 18:1-14; Compl. ¶ 11.⁴) During the surgery, Dr. Sotereanos implanted the M/L Taper Femoral Stem with Kinectiv Technology ("the device"), a hip implant manufactured, designed, and sold by Zimmer. (Sotereanos Dep. at 18:19-25; 46:20-22; Compl. ¶ 12.) By all accounts, the surgery was a success. (Compl. ¶ 12.)

At the time of surgery, Mr. Kline was 5'10 and 255 pounds with a BMI of 36.6. (McClain Rpt. at 6-7.)⁵ People with a BMI of 30 or greater are considered to be obese. (McClain Rpt. at 6.)

Zimmer provided a package insert that accompanied the device, which warns the surgeon

¹ As explained below, Defendants previously filed the first two motions and on November 3, 2014, a Report and Recommendation was filed, recommending that the motion for summary judgment be granted and the motion in limine be dismissed as moot. However, after Plaintiffs indicated that they wanted to submit further evidence not in the record, the R&R was vacated and the parties were directed to re-brief the issues with all of the evidence.

² Defs.' App. (ECF No. 49) Ex. 1. The parties have not refiled the exhibits they previously submitted, so most of the references will be to their originally filed appendixes.

³ ECF No. 49 Ex. 2.

⁴ Notice of Removal (ECF No. 1) Ex. A.

⁵ ECF No. 49 Ex. 4.

that “heavy” patients are at increased risk for failure and that heavy or physically active individuals are particularly at risk. (McClain Rpt. at 5; Pls.’ App. H at 4.⁶) Zimmer states that several of the warnings provided in the package insert refer to the increased risk associated with a patient’s size, activity level and the potential for the device to fracture. (Truman Dep. at 145:1-148:2.)⁷

However, Dr. Sotereanos has stated that:

The package insert does not mention a fracture of the femoral neck after implantation as a risk of the implant.

A “warning” which indicates that “complications or failure of any total hip prosthesis are more likely to occur in heavy patients” is a general statement that is accurate and obvious to any surgeon in the orthopedic community. The overwhelming majority of my patients and of patients nationwide who undergo total hip [arthroplasty] procedures are those who could be classified as “heavy” patients. However, the warning does nothing to indicate how “heavy” a patient must be before a fracture of the modular femoral neck becomes a foreseeable risk. In fact, the term “heavy” is not one used in the medical community because it is a useless, relative term which has been replaced by BMI. Zimmer has never contraindicated the use of the Zimmer M/L Taper Femoral Stem with Kinectiv Technology based on a patient’s BMI.

(Sotereanos Aff. ¶¶ 12-13.)⁸ In addition, when shown the package insert warning stating that “Physical activity can result in loosening, wear, and/or fracture of the hip implant,” Dr. Sotereanos testified that he “would consider that statement absurd. Physical activity, jumping out of an airplane or jumping from a three-story building, yes. But physical activity related to what? Normal activities of daily living? That is, to me, a very vague and absurd statement.” (Sotereanos Dep. at 63:13-19.) On the other hand, Dr. Sotereanos agreed with the package insert statements that “complications or failure of any total hip prosthesis are more likely to occur in heavy patients” and “complications

⁶ ECF No. 52.

⁷ ECF No. 49 Ex. 5.

⁸ Pls.’ Am. App. (ECF No. 80) Ex. J.

and/or failure of total hip prosthesis are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients who fail to follow through with the required rehabilitation program.” (Sotereanos Dep. at 61:25-62:22.)

Dr. Sotereanos admitted that he did not read the package insert that accompanied the device, because he never reads them for any device he implants. (Sotereanos Dep. at 57:20-22.) Rather, he states that Zimmer has provided him (and he believes, other orthopedic surgeons) with important information regarding its products in the following ways:

- a. Zimmer has a listing of every physician who uses its products and provides emails, letters, and brochures about its products to each physician.
- b. Zimmer has a listing of every orthopedic surgeon through the American Academy of Orthopedic Surgeons and Zimmer provides all pertinent information about its products by email, letters, and brochures to each member.
- c. Zimmer utilizes sales representatives to provide physicians with important information about its products including uses, indications, contraindications, risks and warnings.
- d. Zimmer places a Zimmer representative in the OR for all procedures performed using its product who provides any important information to me regarding the product.
- e. Zimmer’s product is reviewed in peer reviewed medical journals which discuss any important information regarding the product.

(Sotereanos Aff. ¶ 6.) In addition, he states that:

At the time of Gregory Kline’s primary surgery, I was aware of all of the recommendations, indications for use, contraindications for use, restrictions, limitations, and warnings about the device from my design work at Zimmer while developing the device, in addition to information provided to surgeons by Zimmer in letters, meetings and seminars, peer-reviewed medical literature and Zimmer representatives including representatives who were actually present in the OR with me during every procedure.

There is nothing in the package insert that I was not aware of from Zimmer, as set forth above.

(Sotereanos Aff. ¶¶ 7-8.) Finally, he states that:

Zimmer has never indicated by any means including the package insert that

patients above a certain BMI are likely to experience a catastrophic failure of their device due to fracture of the modular femoral neck in the Zimmer M/L Taper Femoral Stem with Kinectiv Technology. In my experience, the risk of a fracture of the modular femoral neck is a new risk of failure due to the multi-modularity of the device that did not exist with monoblock devices.

(Sotereanos Aff. ¶ 14.)

According to Defendants' expert, Dr. Edward J. McClain, every orthopedic surgeon who performs total hip arthroplasty is aware of the risks and benefits of modular tapers. (McClain Rpt. at 5.) Dr. McClain stated that every arthroplasty surgeon is also aware that the risk of implant failure is greater in overweight patients that routinely apply heavy loads to their hip. (McClain Rpt. at 5.) Plaintiffs respond that, as Dr. Sotereanos explained, the package insert did not warn of the specific risk of fracture of the femoral neck, and the insert vaguely referred to "heavy" patients without reference to BMI or any specific measurement. (Sotereanos Aff. ¶¶ 12-14.)

Following the surgery, Mr. Kline returned to Dr. Sotereanos on March 2, 2010, at which time Mr. Kline indicated that he wanted to return to his job as a school bus driver and Dr. Sotereanos noted: "We think he can be returned to his regular duties, whatever he wishes, as he has metal-on-metal articulation." (Sotereanos Dep. at 23:17-19.) Dr. Sotereanos went on to explain that, at that time, he did not set any restrictions on his patients with metal-on-metal articulation. (Sotereanos Dep. at 24:2-5.)

On February 15, 2011, Mr. Kline came to Dr. Sotereanos for a follow-up appointment, at which time he indicated that in September 2010, he had begun working for Lowe's Home Improvement delivering heavy appliances like washers and dryers. (Kline Dep. at 18:19-22, 69:1-7; 70:1-14; Sotereanos Dep. at 24:12-18.) Dr. Sotereanos testified that this information caused him no concerns regarding the stability of his hip implant. (Sotereanos Dep. at 24:22-

25:1.) Mr. Kline also complained of problems and pain when sitting or lying down but not when walking, which caused Dr. Sotereanos to conclude that he had tendinitis (which is common after a hip replacement) and he advised Mr. Kline to limit his lifting as much as possible. (Sotereanos Dep. at 25:2-18.) However, he set no weight restrictions. (Sotereanos Dep. at 25:16-18.)⁹

According to Dr. McClain, this new job resulted in greater loads being applied to Mr. Kline's hip on a regular basis. (McClain Rpt. at 2, 5.) For instance, pushing, pulling and lifting heavy loads such as bags of cement, sheets of drywall and washers and dryers and other heavy household appliances exceed the reasonable activity level of a total hip patient. (McClain Rpt. at 5.) However, as noted above, Dr. Sotereanos testified that he had no concerns about the hip replacement based on Mr. Kline's job making deliveries of heavy items for Lowe's. (Sotereanos Dep. at 24:19-25:1.) In addition, Mr. Kline testified that either a fork lift or a hand dolly was used to load the appliances on the delivery truck (Kline Dep. at 71:1-5), that there were always two workers delivering appliances (Kline Dep. at 71:6-12) and that the trucks used to deliver appliances had lift gates to lift appliances up and down (Kline Dep. at 72:8-13). As stated by Mr. Kline: "When you have two people, there's really hardly no lifting. The appliances are always on the dolly." (Kline Dep. at 113:20-22.)

On April 6, 2011, while making deliveries for Lowe's, Plaintiff jumped or stepped down two to three feet off of the back of a delivery truck, whereupon the device fractured at the femoral neck. (Sotereanos Dep. at 26:6-11; McClain Rpt. at 5.) On April 11, 2011, Dr. Sotereanos performed a second surgery ("revision surgery") on Mr. Kline's right hip, removing

⁹ Defendants' statement that, after the surgery, Dr. Sotereanos advised Mr. Kline to limit his lifting as much as possible (ECF No. 72 ¶ 13) is misleading, as is the statement (based on Dr. McClain's report, but not any testimony from Dr. Sotereanos) that Mr. Kline was released with the understanding that he was returning to work as a school bus driver (ECF No. 72 ¶ 14), because Dr. Sotereanos testified that he did not have any concerns about the hip replacement regardless of Mr. Kline's job. These statements should be disregarded.

the device and replacing it with a different implant. (Compl. ¶¶ 22, 27; Sotereanos Dep. at 36:8-12, 70:7-15.)

Defendants note that there were no signs of adverse tissue reactions or corrosion in the operative report from the April 11, 2011 revision surgery. (McClain Rpt. at 6.) They further contend that Plaintiff's expert, Dr. Donald Koss, admitted that he did not have any evidence to prove his speculative theory that the crack that ultimately resulted in the device fracture was "formed due to a localized corrosion/stress-corrosion process." (Koss Dep. at 81:1-3, 84:14-16, 88:13-18.)

Plaintiffs respond that, in his report Dr. Koss explained that an examination of the fracture surface within the region where the crack began using a Scanning Electron Microscope:

indicate[s] that extensive corrosion attack of the fracture surface has occurred within the crack initiation region. Further confirmation of the corrosion attack is shown in Figure 6, where the contrasting appearance of the fracture immediately before and after the crack arrest is shown. In Figure 6b, corrosion attack along interfaces within the metallurgical microstructure is again very obvious.... [T]he fracture surface is dominated by fine scale features consistent with plasticity-induced crack growth, such as metal fatigue.

(Koss Rpt. at 5.)¹⁰ Earlier in the report, Dr. Koss noted that "[m]odular hip taper joints are known to be prone to fretting corrosion, and the alloy used in the present case ... is no exception." (Id. at 3.) Dr. Koss then stated: "Taken together with our earlier assessment of the potential role of localized corrosion in contributing to the fracture of the implant neck, Figures 5 and 6 confirm the aggressive nature of the environment in attacking the Ti alloy in the crack initiation region." (Id. at 5.)

Defendants assert that Plaintiffs' engineering expert, Mari Truman, admits that she has no opinion on the design of the device. (Truman Dep. at 204:19-22.) Ms. Truman joked that she

¹⁰ ECF No. 52 Ex. D.

“even forgot that [she] put the word ‘design defect,’ in [her report]” and that she “had to put it in with [many] qualifications.” (Truman Dep. at 204:23-205:1.) They assert that the fact that Ms. Truman found it necessary to include these qualifications led her to conclude at her deposition that she, in fact, has no theory of defective design. (Truman Dep. at 205:2-4.)

Plaintiffs respond that Ms. Truman’s deposition and report, taken as a whole, indicate that she did find a design defect. They point to the conclusion section of her report, in which she wrote that:

ZIMMER’s design team failed to evaluate the combined effects of reasonably foreseeable loads in an aggressively corrosive (acidic) physiologic environment on the endurance of the Kinectiv Technologies modular components. ZIMMER’s failure to assure that this hip implant would not prematurely crack and fatigue under known and foreseeable physiologic loading in this environment (ACF test) contributed to the lack of information required to generate adequate warnings and is, in this manner, a design defect and caused Gregory Kline’s injuries.

(ECF No. 52 Ex. B at 43 ¶ 3.) See also id. ¶ 4 (failure to thoroughly test of the new implant component fracture risks introduced due to modularity deprived Mr. Kline of level of protection that other non-modular hip stems provide, and failure to use more additional more effective production processes to reduce risk of tensile overload, crack initiation and to retard crack growth likely contributed to premature failure); ¶ 5 (had Zimmer completed fatigue retarding processes to increase the fatigue life of the implants to prevent fatigue cracks and to mitigate fatigue crack propagation in the implant, Kline’s hip implant would have lasted longer and would have been less likely to have prematurely failed, causing his injuries); ¶ 6 (Kline did not act or react improperly in a manner that contributed to his injury); ¶ 7 (Zimmer exposed him to hazards of premature implant loosening and fracture and subsequent bone and soft tissue injury, pain and revision total hip surgery, and the combination of hazard and exposure makes the implant unreasonably dangerous and unsuitable for its intended purpose in higher demand

patients like Kline).

Plaintiffs point out that Ms. Truman indicated that Zimmer's Accelerated Corrosion Fatigue (ACF) testing did not apply the worst case physiologic stresses to the modular connection as the ACF test used peak loads below that of Zimmer's fatigue test. (Truman Rpt. at 22.) She also found fault with the acidity of the solutions in which Zimmer performed the ACF testing because it was not acidic enough to cause the type of corrosion that would be expected when the implant was in the human body. (Id.) She notes that Zimmer had previously developed a test for evaluating the effects of a corrosive environment on modular implant connections, which was discussed in a 1997 ASTM publication. The previously developed test used a more acidic solution, and she questioned whether the ACF test, with its less acidic solution and higher frequency, truly represented the worst case environment as it may not have allowed sufficient time to corrosion reactions. (Id. at 22, 24.) Ms. Truman explained that other medical device manufacturers such as Exactech, Biomet and Depuy, have used production processes such as lower plasticity burnishing (LPB) or laser shock peening (LSP) to increase the fatigue strength of this device and that such processes were in use and available when this device was being designed. (Id. at 25-30.)

Plaintiffs note that, at her deposition, Ms. Truman stated that: "The design defect is in this category of device where you have the modular connection in an area which we previously didn't have." (Truman Dep. at 198:18-20.) She went on to explain that, before the neck-stem modular junction was implemented, she was unaware of basilar neck fractures in the monoblock (stem consisting of a single piece of material as opposed to interlocking pieces) hip device, therefore a new risk of fracture was created with the new design. (Truman Dep. at 198:16-199:3.) Defendants respond that Ms. Truman was then asked about her involvement in the

design of a multiple modularity device and she responded that such a device was not defective if “put out with sufficient warnings,” and that, “in essence, it’s a warnings defect case.” (Truman Dep. at 201:9-10, 16-17.)

Plaintiffs’ other expert, metallurgist Donald Koss, Ph.D., concedes that he was not asked to review or comment on the design of the device in this case. (Koss Dep. at 33:19-22.)¹¹ Defendants note that Dr. Koss stated that he was not “an expert in design” and was “not in a position to judge the design [or] the choice of design” of the device. (Koss Dep. at 33:9-16, 108:8; 101:3-4.) Dr. Koss had no opinions on the design of the device in his report. (Koss Dep. at 101:21-102:6.) Plaintiffs respond that Dr. Koss also stated that he had concerns about “the choice of material in this design” and that the device “failed in a process that I feel will happen again.” (Koss Dep. at 101:25-102:3.) Thus, Plaintiffs maintain that Dr. Koss draws a distinction between his inability to opine on the general design of the device and his ability to opine as to the choice of metal alloy used in the device.

They also note that, when asked if he had any criticisms of Zimmer’s use of the titanium alloy in this device, Dr. Koss responded:

A. Only that it appears susceptible to failure, the mode that I’m describing, which then, I guess, raises the question, well, other implants failed in a similar manner.

Q. Say that again?

A. Will other implants fail in a similar manner so I only see this one and you’ve got this corrosion assisted crack initiation problem, will that occur again. The same material, same processing, same microstructure, heavy patient. It would seem to me that the ingredients are there for such bad surprises to occur again.

(Koss Dep. at 99:2-13.) When asked about the use of the titanium alloy in this device, he said:

“Well, I think such a fracture will occur again in Ti6Al4V, so if you want to use that as a sole

¹¹ ECF No. 49 Ex. 6.

basis for making choice, I guess, the answer would be maybe Zimmer should use a different material but I have no idea what that material would be.” (Koss Dep. at 103:13-17.)

Defendants respond that Dr. Koss was asked if Zimmer should not have used this titanium alloy and he stated “I don’t think I can adequately answer that.” (Koss Dep. at 103:7.) He further indicated that:

I don’t know enough about it to make any sort of educated choice. All I know is I see[] a fracture event which I feel will occur again, and that is related to corrosion. And I don’t know the consequences of that and whether a different material will be better, whether you just live with some of these fractures. I don’t know the entire – it that’s [sic] a complicated question and I don’t think I’m in any position – I’m just a metallurgist identifying a cause of failure.

(Koss Dep. at 103:17-104:1.) Plaintiffs note that Dr. Koss received M.S. and Ph.D. degrees in metallurgy from Yale University and became the Chairman of Metals Science and Engineering and professor of Materials Science and Engineering at Penn State University in 1986. (Koss Rpt. App. at 1.) At his deposition, he testified that he has written or contributed to over 50 publications related to titanium alloys. (Koss Dep. at 12:16-23.) He has over 50 years of experience working with fracture processes in titanium alloys, fatigue fracture and stress corrosion cracking. (Koss Dep. at 14:18-23.) In the 1970s and 1980s, he received funding from the United States Air Force and Navy to research titanium alloys. (Koss Dep. at 21:16-18.)

Defendants argue that, because Dr. Koss admitted that he is not an expert in design and framed his comment about Zimmer using another alloy as a “maybe” immediately followed by an admission that he had no idea what the other material would be, Plaintiffs are relying on unsupported speculations and that the Court of Appeals “has emphasized that mere ‘theoretical speculations’ lacking a basis in the record will not create a genuine issue of fact.” Marvel v. Delaware County, 2009 WL 1544928, at *17 (E.D. Pa. June 2, 2009) (citing Pennsylvania Dental Ass’n v. Medical Servs. Ass’n of Pa., 745 F.2d 248, 262 (3d Cir. 1984)).

Ms. Truman did not offer any opinion as to whether the device had a manufacturing defect. (Truman Dep. at 253:13-16.) Dr. Koss was not asked to “review or comment on the manufacturing process used in manufacturing the components used in Mr. Kline” and knows “nothing of the manufacturing process.” (Koss Dep. at 35:23-36:3.) He had “no opinion” on the design of the components used in the device. (Koss Dep. at 35:13-16.)

Ms. Truman admitted that Zimmer did not fail to comply with any of the American Society for Testing and Material (“ASTM”) standards listed on her report. (Truman Dep. at 124:15-18.) Ms. Truman acknowledged, on several occasions, that Zimmer’s testing met or exceeded the industry standards and was more than sufficient. (Truman Dep. at 152:5-14, 153:1-4, 187:25-188:20, 189:25-190:6.) Plaintiffs respond that, although Ms. Truman conceded that Zimmer’s testing in general met or exceeded industry standards, she expressed the opinion in her report that the testing was not thorough enough. (ECF No. 52 Ex. B at 43.)

Dr. Koss did not know the standards for fatigue and testing in medical devices. (Koss Dep. at 38:24-39:1.) Dr. Koss conceded that he has no experience with designing or manufacturing medical devices. (Koss Dep. at 31:22-32:6, 38:15-39:13.)

Plaintiffs state that Zimmer’s staff engineer, Steven Meulink, testified that the parameters of the ACF test discussed in the 1997 ASTM STP 1301 publication, such as elevated temperatures, reduced pH, load and frequency, were chosen to reproduce the corrosion that occurs in the body. (Meulink Dep. at 77:9-78:12.)¹² They note that Defendants’ own expert, Dr. Steven Kurtz, testified that he was unable to think of any examples of any fractures of the neck portion of monoblock hip stems. (Kurtz Dep. at 140:6-13.)¹³ Dr. Kurtz was then asked whether a fracture at the neck-stem junction was a “new risk” that was introduced with modularity, and

¹² ECF No. 52 Ex. F.

¹³ ECF No. 52 Ex. G.

he responded “Yes. It’s a new location for the well-established risks of fretting, fatigue, and corrosion to take place in a new location because of the new design of the implant.” (Kurtz Dep. at 140:14-20.)

Zimmer’s warnings are contained in a document that accompanied the device called a package insert. (McClain Rpt. at 6.) Defendants note that FDA regulations, specifically 21 C.F.R. § 801.5, require it to include labeling within the package of the device indicating its indications, effects, routes, methods and frequency and duration of administration, and any relevant hazards, contraindications, side effects and precautions.¹⁴ In addition, they note in their reply brief that 21 C.F.R. § 801.109(c) specifically requires warnings and other information to be stated “on or within the package” from which a prescription medical device is dispensed.

Dr. Sotereanos has never read a package insert for any device he has implanted. (Sotereanos Dep. at 57:20-22.) Dr. Sotereanos did not see, let alone read, the package insert that accompanied Mr. Kline’s device. (Sotereanos Dep. at 61:7-9.) It is standard practice for nurses in the operating room to open device packages without surgeons ever seeing the warnings attached therein. (Sotereanos Dep. at 61:10-20.) Dr. Sotereanos was not aware of Zimmer’s warnings contained therein related to the use of the device in heavier or more physically active patients. (Sotereanos Dep. at 62:23-63:3.) However, he agreed with the statement in the warning that failure is more likely in heavier or more active patients. (Sotereanos Dep. at 62:5-7.) He was also independently aware of the risks of total hip arthroplasty, including that an implant can break, from his practice and reading literature. (Sotereanos Dep. at 57:13-19.)

Ms. Truman concluded that all of Zimmer’s warnings were accurate, but she wished that

¹⁴ Plaintiffs deny this statement on the ground that Defendants failed to cite the regulation in their concise statement (ECF No. 72 ¶ 37). Nevertheless, Defendants do cite the regulation in their brief (ECF No. 71 at 7).

Zimmer was “more aggressive” with respect to warnings about the effect of patient weight and activity levels. (Truman Dep. at 138:16-24, 148:3-6.) Defendants argue that Ms. Truman offers no standard upon which to base these wishes and concedes that Zimmer’s package insert provided at least seven separate warnings related to implant fracture, of which three relate to the specific size and activity level of a patient to prevent fracture. (Truman Dep. at 147:24-148:2.) However, Plaintiffs respond that she provided a table from another company, Exactech’s AcuMatch M modular femoral system, which specifically contraindicates the use of the device in a patient weighing over 250 pounds with anything more than a sedentary activity level. (ECF No. 52 Ex. B at 32.)

Ms. Truman admitted that “weight alone is a difficult thing to warn” in a medical device such as this and that is why she suggested warning about the “combination of activity and weight, not just weight alone” and she believes “[i]t’s more the activities that are the problem.” (Truman Dep. at 161:8-23.) Defendants note that the FDA does not require contraindicated patient weight limits in the labeling for femoral hip stem systems. (Defs.’ Am. App. Ex. 7 at 11.)¹⁵ Plaintiffs respond that the document uses the word “generally,” thereby implying that there may be situations in which such a contraindication is needed. They further respond that compliance with FDA regulations and recommendations alone does not guarantee that a medical device is not defective and incapable of causing unreasonable harm to its intended users.

Dr. Koss is not an expert in the warnings that accompany medical devices, and he was not asked to review or make any comment about the warnings that accompanied the device in this case. (Koss Dep. at 35:20-36:9.) Dr. Koss has no opinion on what warnings ought to accompany the device in this case. (Koss Dep. at 101:17-20.)

¹⁵ ECF No. 73.

Dr. McClain states that Zimmer's package insert for the device "clearly and unequivocally warns the surgeon that heavy patients are at increased risk for failure and that 'heavy or physically active patients are particularly at risk.'" (McClain Rpt. at 6.) He believes that the package insert also provides thorough and adequate warnings to the surgeons. (McClain Rpt. at 6.) Plaintiffs respond that, when Dr. Sotereanos was asked about the statement "Physical activity can result in loosening, wear, and/or fracture of the hip implant," he responded: "I would consider that statement absurd. Physical activity, jumping out of an airplane or jumping from a three-story building, yes. But physical activity related to what? Normal activities of daily living? That is, to me, a very vague and absurd statement." (Sotereanos Dep. at 63:13-19.)

Dr. McClain further states that "every orthopedic surgeon who performs total hip arthroplasty is aware of the risks and benefits of modular tapers," including that "the risk of implant failure is greater in overweight patients that routinely apply heavy loads to their hip." (McClain Rpt. at 5.) Plaintiffs deny that Dr. McClain can speak for the specific knowledge of "every orthopedic surgeon."

Ms. Truman is not an orthopedic surgeon and is not offering an opinion on medical causation because she is not qualified to do so. (Truman Dep. at 73:20-74:3.) Dr. Koss has no medical training and is not an orthopedic surgeon. (Koss Dep. at 31:2-3.) Defendants argue that Dr. Koss acknowledged that his medical causation testimony was speculative. (Koss Dep. at 50:25-51:1; 84:14-16; 88:13-18.) Plaintiffs respond that Dr. Koss testified that he could not speak with 100% certainty, but he expressed his opinions with 98% certainty. (Koss Dep. at 96:18-25.)

When asked if he ruled out potential causes of the initiation of Mr. Kline's implant crack, Dr. Koss stated that he "saw no reason to because to me the critical event is that there was a

crack initiation stage that resulted in subsequent fatigue crack growth that caused failure of the implant.” He could not say whether there was fretting. (Koss Dep. at 89:4-17.)

According to Dr. McClain, the failure of the device was “no surprise,” given Mr. Kline’s “weight, his job requirements, his heavy lifting, and regular loading to his hip.” (McClain Rpt. at 6-7.) This “case represents a failure of the patient to reasonably protect his total hip replacement” because Mr. Kline “engaged in work and daily activities that were detrimental to the survivorship of the implant,” “did not reduce his BMI below the obese level,” “did not discuss with his surgeon the fact that he was engaging in a job that had significant physical demands,” and “did not avoid impact loading activities.” (McClain Rpt. at 7.) Dr. McClain opined that Mr. Kline’s weight and activity level “amounts to the perfect storm” for failure of the device. (McClain Rpt. at 6.) Plaintiffs deny that Dr. McClain’s conclusions are accurate.

Dr. McClain has implanted the M/L Taper Femoral Stem with Kinectiv Technology in 369 hips without any neck fractures. (McClain Rpt. at 4.) Dr. Sotereanos testified that he has implanted between 300 and 500 Kinectiv stems. (Sotereanos Dep. at 9:2-14.) When he learned that two of his patients (Mr. Kline being one of them) experienced fractures of the Kinectiv neck, he “no longer could medically recommend the implant being used.” (Sotereanos Dep. at 47:14-20.) In fact, he co-authored a case study in which the subject was Gregory Kline’s failed device and the co-authors of the publication concluded “The authors would recommend against routine use of a modular femoral stem in the primary setting unless it is absolutely necessary to achieve stability intraoperatively.” (Sotereanos Dep. at 46:25-47:4.) Dr. Sotereanos’s knowledge of the device began when he was member of a design team consisting of several surgeons that were involved in the design of this very device. (Sotereanos Dep. at 8:3-9:1.) Dr. Sotereanos also testified that it is his personal practice to have a representative of the device manufacturer in the

operating room during his implant surgeries to ensure that the appropriately sized implants are used and that all appropriate instrumentation is available. (Sotereanos Dep. at 19:14-20:3.)

Procedural History

Plaintiffs filed this action in the Court of Common Pleas of Allegheny County, Pennsylvania on March 15, 2013. Count I alleged that Defendants were negligent in the preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of the hip implant components and that this negligence caused Mr. Kline's injury. Count II alleged claims of strict liability based on design defects, manufacturing defects and a failure to warn. Count III alleged claims of breach of the implied warranties of merchantability and fitness for a particular purpose. Count IV alleged a claim of breach of express warranties. Count V alleged a derivative claim of loss of consortium on behalf of Cherrie Kline.

On April 9, 2013, Defendants removed the case to this Court, asserting diversity of citizenship jurisdiction in that: Plaintiffs are Pennsylvania citizens; Zimmer is a Delaware corporation with its principal place of business in Warsaw, Indiana; and the amount in controversy, exclusive of interest and costs, exceeds the sum of \$75,000.00. (Notice of Removal ¶¶ 7-15.) On April 12, 2013, Defendants filed an answer to the complaint (ECF No. 7). On May 3, 2013, they filed a partial motion to dismiss, which was treated as a partial motion for judgment on the pleadings (ECF No. 12).

On June 27, 2013, an order was entered (ECF No. 23), adopting a Report and Recommendation that was filed on May 31, 2013 (ECF No. 20) and granting the motion in part and denying it in part, as follows: as to the strict liability claims in Count II, the motion was granted with respect to Plaintiffs' design defect and failure to warn claims, but denied with

respect to Plaintiffs' manufacturing defect claim; as to the breach of implied warranties claims in Count III, the motion was granted with respect to Plaintiffs' claim of breach of the implied warranty of fitness for a particular purpose and the claim of breach of implied warranty of merchantability based upon the design defect and failure to warn claims, but denied with respect to Plaintiffs' claim of breach of the implied warranty of merchantability based upon a manufacturing defect; as to the breach of express warranties claims in Count IV, the motion was granted. Thus, the remaining claims at that time were Gregory Kline's negligence claim (Count I), his strict liability manufacturing defect claim (in Count II), his breach of implied warranty of merchantability claim based upon a manufacturing defect (in Count III), and Cherrie Kline's loss of consortium claims associated with Gregory's remaining claims of recovery (Count V).

On August 29, 2014, Defendants filed a motion for summary judgment (ECF No. 47), along with a brief in support (ECF No. 48), and a concise statement of material facts with exhibits in an appendix (ECF No. 49). On that same date, they also filed a motion in limine to exclude specific opinions of Plaintiffs' expert witnesses (ECF No. 45). On September 30, 2014, Plaintiffs filed a brief in opposition to the motion for summary judgment (ECF No. 53), a counterstatement of material facts (ECF No. 51) and an appendix with exhibits in support thereof (ECF No. 52). They also filed a brief in opposition to the motion in limine (ECF No. 50). On October 10, 2014, Defendants filed a reply brief (ECF No. 54) and response to Plaintiffs' statement of material facts (ECF No. 55).

On November 3, 2014, a Report and Recommendation was filed (ECF No. 58), which recommended that Defendants' motion for summary judgment be granted and that the motion in limine be dismissed as moot. Objections were due on November 17, 2014, but Plaintiffs requested and received an extension of time until December 17, 2014 (ECF No. 59; text order

dated November 13, 2014). On December 17, 2014, Plaintiffs filed a second motion for extension of time, in which they asked for only two additional days, but indicated that they wished to submit “further evidence” in opposition to the motion for summary judgment. On December 18, 2014, Chief Judge Conti granted this motion only insofar as it sought an extension of time, but denied it insofar as Plaintiffs wished to submit further evidence. Judge Conti directed Plaintiffs to seek such relief before the magistrate judge (ECF No. 62).

Later that day, Plaintiffs filed an emergency motion to modify (ECF No. 63) and brief in support (ECF No. 64), in which they contended that, pursuant to Federal Rule of Civil Procedure 72(b)(3), the district judge may “receive further evidence” in ruling on objections to a report and recommendation. On December 19, 2014, Judge Conti entered an order recommitting and returning the matter to the undersigned to consider whether to accept further evidence (ECF No. 65). On December 22, 2014, an order was entered, directing Plaintiffs to submit a brief in support of the Court considering further evidence by December 26, 2014 and directing Defendants to submit any opposition by January 2, 2015 (ECF No. 66). Plaintiffs filed their brief as directed (ECF No. 67), and Defendants did so as well (ECF No. 68).

On January 5, 2015, an order was entered, vacating the Report and Recommendation, dismissing the motion for summary judgment and motion in limine without prejudice and directing the parties to re-brief the matter with all supporting documents (ECF No. 69).

On January 20, 2015, Defendants filed an amended motion for summary judgment (ECF No. 70) and an amended motion in limine (ECF No. 74). On February 3, 2015, Plaintiffs filed briefs in opposition (ECF Nos. 78, 81). On February 10, 2015, Defendants filed a reply brief with respect to the summary judgment motion (ECF No. 82), as well as a motion to strike the affidavits of Ms. Truman and Dr. Sotereanos (ECF No. 84) that Plaintiffs had submitted with

their opposition. Plaintiffs filed their brief in opposition to the motion to strike on February 18, 2015 (ECF No. 87).

Motion to Strike

Defendants move to strike the affidavits of Ms. Truman and Dr. Sotereanos that Plaintiffs submitted with their response in opposition to the motion for summary judgment. With respect to Ms. Truman's affidavit, they argue that: 1) it is a sham affidavit because it contradicts her sworn deposition testimony, in which she admitted that her theory of the case was one of defective warnings, not defective design; and 2) it is untimely because expert discovery was to be completed by June 14, 2014 and her failure to comply with the Federal Rules of Civil Procedure was not harmless or justified. With respect to Dr. Sotereanos's affidavit, they argue that: 1) it contains inadmissible statements that cannot be based on his personal knowledge; 2) it contradicts his prior deposition testimony; and 3) it offers expert testimony although he was not disclosed as an expert witness but rather as Mr. Kline's treating physician. In addition, Defendants argue that both affidavits improperly include discussion of Robert Leshner, another patient of Dr. Sotereanos's who suffered a fracture of a Zimmer hip implant and who filed a complaint that has since been voluntarily dismissed.

In response, Plaintiffs argue that: 1) the Court has already ruled upon this issue and indicated that the affidavits would be considered; 2) Ms. Truman's affidavit does not provide any new design defect or warning defect opinions, but merely explains the opinions contained in her expert report and deposition testimony; 3) Ms. Truman's affidavit is not untimely because an expert may supplement a report until 30 days before trial or by the time pretrial disclosure are due and they have not been scheduled; 4) all statements made by Dr. Sotereanos are based on his personal knowledge; 5) Dr. Sotereanos does not contradict his prior testimony; 6) Dr. Sotereanos

does not offer opinions, but factual statements regarding his personal knowledge of the device at issue, his personal understanding of the warnings for the device, his personal experience with Zimmer in terms of communication and a substantially similar device failure in another patient; and 7) the existence of the Leshner case is relevant because it involves the same medical device, the same treating surgeon and the same mode of device failure.

Plaintiffs are correct that the Court has directed that they may submit further evidence in opposition to Defendants' motion for summary judgment and that Ms. Truman's affidavit is not untimely under the Federal Rules of Civil Procedure. Nevertheless, the fact that the Court has permitted Plaintiffs to submit these affidavits does not mean that everything in them may be considered. On the other hand, Defendants have not demonstrated that a motion to strike is the proper procedural vehicle to raise this issue.

Pursuant to Federal Rule of Civil Procedure 12(f), upon a motion by either party, the "court may strike from a pleading ... any redundant, immaterial, impertinent, or scandalous matter." Fed.R.Civ.P. 12(f). The purpose of a Rule 12(f) motion to strike is to "clean up the pleadings, streamline litigation, and avoid the unnecessary forays into immaterial matters." United States v. Educ. Mgmt. Corp., 871 F. Supp. 2d 433, 460 (W.D. Pa. 2012) (McVerry, J.) (citation omitted). The movant must show that the allegations being challenged are so unrelated to the plaintiff's claims as to be unworthy of any consideration and that their presence in the pleadings will be prejudicial. Flanagan v. Wyndham Int'l, Inc., 2003 WL 23198798, at *1 (D.V.I. Apr. 21, 2003) (citing 2 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure, § 1380); River Rd. Dev. Corp. v. Carlson Corp.-Northeast, 1990 WL 69085, at *7 (E.D. Pa. May 23, 1990) (the movant "must clearly show that the matter sought to be stricken is outside the issues in the case and is prejudicial" on a Rule 12(f)(2) motion).

Although courts possess considerable discretion in disposing of a motion to strike under Rule 12(f), Thornton v. UL Enters., 2010 WL 1005021, at *2 (W.D. Pa. Mar. 16, 2010) (Cohill, J.), “striking a pleading is a ‘drastic remedy’ to be used sparingly because of the difficulty of deciding a case without a factual record.” Dann v. Lincoln Nat. Corp., 274 F.R.D. 139, 142 (E.D. Pa. 2011); see also Tennis v. Ford Motor Co., 730 F. Supp. 2d 437, 443 (W.D. Pa. 2010) (McVerry, J.) (“Striking some or all of a pleading is therefore considered a drastic remedy to be resorted to only when required for the purposes of justice.”) (citation omitted).

This Court has observed that “a motion to strike is only applicable to responsive pleadings.” Tauro v. Baer, 2009 WL 2410952, at *2 (W.D. Pa. Aug. 4, 2009) (Conti, J.) Pleadings are defined in Rule 7(a) to include the complaint, answer and third-party complaints and answers, and “thus motions, affidavits, briefs, and other documents outside of the pleadings are not subject to Rule 12(f).” Federal Practice & Procedure § 1380 & n.8.5. See GRS Dev. Co. v. Jarrett, 2003 WL 21134437, at *3 (V.I. Apr. 10, 2003) (denying motion to strike response to motion for summary judgment on the basis that a motion for summary judgment is not a pleading and neither the motion nor its contents were amenable to being struck from the record).

Thus, the Court need not strike the affidavits of Ms. Truman and Dr. Sotereanos from the record. However, certain portions of these affidavits cannot be considered, for several reasons.

First, certain statements made by Dr. Sotereanos are not based on his personal knowledge. See Fed.R.Civ.P. 56(c)(2) (“A party may object that the cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence.”); Rule 56(c)(4) (affidavits must be made on personal knowledge). Dr. Sotereanos cannot state from his personal knowledge that: “Zimmer is aware that physicians do not review or see the package insert” (Sotereanos Aff. ¶ 6); that Zimmer “provides all important information regarding the product” in

certain ways (id.); or that Zimmer alerts the orthopedic community of any new contraindications or warnings via means other than the package insert (Sotereanos Aff. ¶ 10).¹⁶ Therefore, these statements will be disregarded.

Moreover, Dr. Sotereanos was not identified by Plaintiffs as an expert witness, but rather as Mr. Kline's treating physician. Portions of his affidavit discuss his role as a paid consultant for Zimmer during the design phase of the device he would later implant in Mr. Kline's hip and what he learned about the device at that time (Sotereanos Aff. ¶¶ 1-5, 11), but he cannot proffer testimony in this capacity.

Rule 26(a)(2)(A) requires a party to "disclose to the other parties the identity of any witness it may use at trial to present" expert testimony. party to "disclose to the other parties the identity of any witness it may use at trial to present" expert testimony. If the witness has been retained specifically for the purpose of providing expert testimony, then the disclosure of the expert must be accompanied by a written report. Fed. R. Civ. P. 26(a)(2)(B). In the case of a treating physician, however, so long as the physician's testimony is limited to testimony regarding his or her treatment, examination, and diagnosis of a party, there is no need for an accompanying written report. Frederick v. Hanna, 2007 WL 853480, at *6 (W.D. Pa. Mar. 16, 2007) (holding that a treating physician not disclosed as an expert may testify to facts within his or her knowledge, that is, testimony about his or her treatment, examination, and diagnosis of a party). See also Calhoun v. Klingensmith Healthcare, Inc., 2007 WL 4205818, at *1-2 (W.D. Pa. Nov. 27, 2007) (limiting the testimony of a treating physician to factual testimony regarding the physician's treatment, examination, and diagnosis of the plaintiff where the physician was

¹⁶ Obviously, Dr. Sotereanos could testify as to how he, as an orthopedic surgeon, received information from Zimmer, which is how Plaintiffs attempt to characterize his affidavit, but Dr. Sotereanos went beyond this statement to aver how Zimmer provides information to everyone.

not identified as an expert in accordance with Rule 26).

On the other hand:

if a treating physician is specifically retained to provide opinion testimony on issues such as causation, that physician must comply with the expert report requirements of Rule 26(a)(2)(B). See Brooks v. Union Pac. R.R. Co., 620 F.3d 896, 900 (8th Cir. 2010) (excluding the causation opinion of a treating physician for failure to comply with Rule 26(a)(2)). Here, the record supports Defendant's characterization of Dr. Miller as a retained expert with regard to his proposed testimony on causation. As noted above, Plaintiff appears to concede this fact as well. Therefore, we find that Dr. Miller is not excepted from the Rule 26(a)(2)(B) expert report requirement.

Brenner v. Consol. Rail Corp., 806 F. Supp. 2d 786, 790 n.4 (E.D. Pa. 2011). In the Brenner case, Dr. Miller opined that the plaintiff's symptoms and degenerative changes were due at least in part to the work he did on the railroad. The court concluded that this testimony fell within Dr. Miller's purview as the treating physician and orthopedic surgeon whose expert qualifications were not being challenged and that the defendants' objections were directed to the weight of his testimony, not its admissibility.

Here, by contrast, Plaintiffs proffer Dr. Sotereanos's affidavit in part to substantiate their claims of negligent design based on his participation in the design of the implant at issue here. In this respect, Dr. Sotereanos is not testifying as Mr. Kline's treating physician, but as an expert. Plaintiffs admit that they did not disclose Dr. Sotereanos as an expert and did not submit an expert report written by Dr. Sotereanos pursuant to Rule 26. (ECF No. 79 ¶ 52.) These portions of the affidavit will be disregarded.

Defendants have not demonstrated that Dr. Sotereanos's affidavit contradicts his deposition testimony in any significant way. They point to the fact that, in the affidavit, he states that the package containing the implant is opened in the operating room by the Zimmer representative (Sotereanos Aff. ¶ 9), but at his deposition he said the nurse opens it (Sotereanos

Dep. at 61:12-17). This is a distinction without a difference because the important fact is that Dr. Sotereanos himself does not open the package and see the insert.¹⁷ Similarly, Defendants note that, in his affidavit, Dr. Sotereanos said that failure of the modular femoral neck in an implant is an unacceptable risk (Sotereanos Aff. ¶ 3), but at his deposition he said that “anything can break” (Sotereanos Dep. at 57:13-15). These statements are not inconsistent.¹⁸

Portions of Ms. Truman’s affidavit encounter the sham affidavit doctrine, which states that “a court will disregard an affidavit that is inconsistent with an affiant’s prior deposition testimony ... unless the party relying on the affidavit in opposition to the motion can present a legitimate reason for the discrepancies between the deposition and the affidavit.” Smith v. Johnson & Johnson, 593 F.3d 280, 285 n.3 (3d Cir. 2010). “The main practical reason supporting the sham affidavit doctrine is that prior depositions are more reliable than affidavits.” Jiminez v. All Am. Rathskeller, Inc., 503 F.3d 247, 253 (3d Cir. 2007).

Ms. Truman’s deposition testimony retreated from her expert report insofar as it alleged a design defect theory, and thus she cannot refer back to her expert report in her affidavit to support a design defect claim that she did not endorse at her deposition (Truman Aff. ¶¶ 1-4).¹⁹ In addition, her affidavit stated that she “opined” that the warnings in the package insert were defective in various ways (Truman Aff. ¶ 5), but she cites no place in her deposition or expert report where this previous opinion can be found.

Finally, both Ms. Truman and Dr. Sotereanos proffer opinions about Robert Leshner, another individual who allegedly had the same implant in his hip which also fractured. (Truman Aff. ¶¶ 6-10; Sotereanos Aff. ¶¶ 18-23.) The Court of Appeals has held that evidence of other

¹⁷ It is also noted that Plaintiffs never refer to paragraph 9 of Dr. Sotereanos’s affidavit.

¹⁸ Again, Plaintiffs never cite this portion of the affidavit.

¹⁹ ECF No. 80 Ex. L.

injuries is not admissible unless the circumstances of the other occurrences are “substantially similar” to those in the case being litigated. Barker v. Deere and Co., 60 F.3d 158, 162 (3d Cir. 1995). The fact that “the evidence of other injuries allegedly involves the same product is not enough to make the evidence admissible even under the liberal standard of admissibility of Fed.R.Evid. 401.” Soldo v. Sandoz Pharms. Corp., 244 F. Supp. 2d 434, 550 (W.D. Pa. 2003) (citations omitted). Plaintiffs have not explained why any information regarding Mr. Leshner and his situation is relevant to this case. It is further noted that, although Mr. Leshner filed a suit against Zimmer (Civ. A. No. 14-1703), he voluntarily dismissed the case on January 31, 2015, prior to any answer being filed.

Summary Judgment Standard of Review

As amended effective December 1, 2010, the Federal Rules of Civil Procedure provide that: “The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed.R.Civ.P. 56(a). Summary judgment may be granted against a party who fails to adduce facts sufficient to establish the existence of any element essential to that party’s case, and for which that party will bear the burden of proof at trial. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). The moving party bears the initial burden of identifying evidence which demonstrates the absence of a genuine issue of material fact. Once that burden has been met, the non moving party must set forth “specific facts showing that there is a genuine issue for trial” or the factual record will be taken as presented by the moving party and judgment will be entered as a matter of law. Matsushita Elec. Indus. Corp. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). An issue is genuine only if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

In following this directive, a court must take the facts in the light most favorable to the non-moving party, and must draw all reasonable inferences and resolve all doubts in that party's favor. Hugh v. Butler County Family YMCA, 418 F.3d 265, 266 (3d Cir. 2005); Doe v. County of Centre, Pa., 242 F.3d 437, 446 (3d Cir. 2001).

Defendants contend that: 1) Plaintiffs have no expert evidence of a design defect; 2) they have no expert evidence of a manufacturing defect; 3) they have no evidence that Zimmer breached a duty of care, thereby precluding a negligence claim, plus there was a package insert that the surgeon did not read, so they cannot maintain a failure to warn claim, and the warnings were adequate in any event; 4) under the latest cases interpreting Pennsylvania law, Plaintiffs cannot maintain a claim for strict liability against a manufacturer of a prescription medical device, even under a manufacturing defect theory; 5) Plaintiffs cannot recover under any theory because they have no expert testimony to establish causation, and the only expert testimony on this topic indicates that Mr. Kline was overweight and worked at a job where he had to perform heavy lifting, both of which put undue amounts of stress on the implant; and 6) any remaining loss of consortium claims will fall with the dismissal of the other claims.

Plaintiffs concede that neither expert has opined that a manufacturing defect exists in the device and that the claims for manufacturing defect and breach of the implied warranty of merchantability fail. They are not pursuing any strict liability claims. (ECF No. 78 at 21.) Thus, Counts II and III should be dismissed and only the negligence claims for a design defect and a warnings defect in Count I and the loss of consortium claims in Count V remain.

However, Plaintiffs contend that: 1) their experts' testimony and reports, when viewed as a whole, rather than "cherry picking" alleged concessions and admissions as Defendants do, are sufficient to allow a jury to conclude that there was a design defect for negligence purposes; 2)

Defendants breached the standard of care by failing to perform testing which adequately mimicked the physiological conditions of the human body, failing to thoroughly test for fracture risks that did not exist prior to the introduction of multi-modularity in the device, failing to use more effective production processes to reduce fracture risks as other medical device manufacturers were doing at the time, and failing to warn adequately about using this device in a high risk patient like Gregory Kline; 3) Ms. Truman opined that Zimmer's warnings were inadequate and her rationale is supported by Dr. Sotereanos; 4) Dr. Sotereanos had comprehensive knowledge of the warnings, precautions and indications for use of this device through his work in designing it and Zimmer never indicated that the femoral neck component may experience a catastrophic failure; 5) the fracture of the femoral neck necessitated revision surgery and both Ms. Truman and Dr. Koss provided admissible opinions as to the cause of the catastrophic fracture; and 6) the failure of Robert Leshner's device, when he was not overweight and not involved in strenuous activity, bolsters Plaintiffs' claim and undermines Defendants' position that Mr. Kline is responsible for the device's failure.

In a reply brief, Defendants argue that: 1) Plaintiffs' experts concede that they hold no opinion about a defect in the design of the device and thus Plaintiffs lack any support for a negligent design defect claim and no amount of creative splicing of their testimony or last-minute affidavits can alter this fact; and 2) Plaintiffs cannot maintain a negligent failure to warn claim because Dr. Sotereanos agreed with the warnings about increased risk in heavier, more active patients when he was presented with them at his deposition and he testified both that he was already aware of the increased risk and that he never reads package inserts, so there is no basis for a conclusion that he would have altered his device selection regarding Gregory Kline if Zimmer had provided "more aggressive" warnings, and the FDA requires warnings to be in

package inserts, not in some other material Dr. Sotereanos claims to have obtained at Zimmer.

Expert Testimony

Defendants argue that, under Pennsylvania law, which the parties agree applies in this case, in order to prove a case of negligence involving a complex product – such as an orthopedic medical device – a plaintiff must present admissible expert testimony that a manufacturer breached its duty failing to exercise due care in the manufacture of a product and that this breach is the proximate cause of the plaintiff's injuries. See Oddi v. Ford Motor Co., 234 F.3d 136, 160 (3d Cir. 2000); Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 754 (E.D. Pa. 2007). Plaintiffs do not contest this point and they have in fact supplied two experts, Mari Truman and Dr. Donald Koss, to attempt to establish their claims.

Negligence Claims

In Count I, Plaintiffs raise two claims of negligence, specifically a claim of negligent design and a claim of negligent failure to warn. Defendants argue Plaintiffs have not presented any expert evidence that they breached any duties or proximately caused the injury. Moreover, they contend that Plaintiffs' negligent failure to warn claim also fails because of the "learned intermediary doctrine." Plaintiffs respond that the expert reports provide evidence in support of the negligent design and the negligent failure to warn and that Dr. Sotereanos had comprehensive knowledge of the warnings, precautions and indications for use of the device through his work in designing it.

Negligent Design

Plaintiffs contend that the device was negligently designed. Defendants argue that Plaintiffs have presented no expert evidence that the device was negligently designed; in fact, both of Plaintiffs' experts have admitted that they hold no opinion that the device was

defectively designed. Plaintiffs respond that, in their reports, the experts expressed the opinion that the device was defectively designed.

“In order to show negligent design and negligent manufacture under Pennsylvania law, plaintiff must show that (1) the manufacturer owned a duty to the plaintiff, (2) the duty was breached and (3) such a breach was the proximate cause of plaintiff’s injuries.” Soufflas, 474 F. Supp. 2d at 753 (citing Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003)). The court then stated that “in order to raise a genuine issue of material fact with respect to the negligent design and negligent manufacture claim, Plaintiff must offer evidence that Zimmer breached its duty. This requires a showing that the Defendant failed to exercise due care in manufacturing or supplying the product.” Id. at 754.

Ms. Truman stated that “in essence, it’s a warnings defect case” (Truman Dep. at 201:16-17); she acknowledged that it was “fair” to say that her defect theory was one of a warnings defect (Truman Dep. at 204:19-22); and she indicated that she “even forgot that [she] put the word ‘design defect’ in there” (Truman Dep. at 204:23-205:4). She further acknowledged that Zimmer’s fatigue test was “state of art in the industry relative to the loads being applied” and that its corrosion test was “more aggressive than the [industry] standard.” (Truman Dep. at 152:5-14, 153:1-4, 187:25-188:20, 189:25-190:6.)

Dr. Koss stated that he was not asked to review or comment on the design of the device (Koss Dep. at 33:19-22); that he is “not an expert in design” (Koss Dep. at 108:8); that he is “not in a position to judge the design [or] the choice of design” of the device (Koss Dep. at 101:3-4); and that he has no opinion on the design of the device in his report (Koss Dep. at 101:21-102:6). When asked if Zimmer should not have used this titanium alloy in making the device, he responded “I don’t think I can adequately answer that” (Koss Dep. at 103:7) and, although he

speculated that “maybe” Zimmer should have used a different material, he immediately stated that “I have no idea what that different material would be,” that he did not know if a different material would be better and he concluded “I don’t think I’m in any position—I’m just a metallurgist identifying a cause of failure.” (Koss Dep. at 103:15-104:1.)

Defendants argue that Dr. Koss’s testimony at most indicates that “maybe” Zimmer should have used a different material (although he did not know what that material would be), an unsupported speculation insufficient to create a genuine issue of material fact on this issue. With respect to Ms. Truman, although certain statements in her report could have supported a negligent design claim, at her deposition, she qualified these statements and concluded that the case was, in fact, one of negligent failure to warn.

In response, Plaintiffs proffer an affidavit of Ms. Truman, signed on November 26, 2014, in which she attempts to rehabilitate the design defect theory. (Truman Aff. ¶¶ 1-4.) However, as explained above, this portion of her affidavit contradicts her deposition testimony and should be disregarded. And, as further explained above, Dr. Sotereanos cannot offer expert testimony about the design of the device from the time he spent as a consultant to Zimmer because he has not been identified as an expert witness in this case and the testimony exceeds his role as treating physician for Mr. Kline.

Thus, Plaintiffs have no expert support for their negligent design theory. With respect to it, the motion for summary judgment should be granted.

Negligent Failure to Warn

“In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs must further establish proximate causation by showing that had defendant issue a proper warning to the learned intermediary, he would have altered his behavior

and the injury would have been avoided.” Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1155 (Pa. Super. 1996) (citation omitted), appeal denied, 684 A.2d 557 (Pa. 1996). See also Soufflas, 474 F. Supp. 2d at 751.

Pursuant to the learned intermediary doctrine, a manufacturer will be held liable only when it fails to adequately warn the intended user, which in the case of prescription drugs or medical devices, is the physician and not the patient. Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 748 (W.D. Pa. 2004); Rosci v. AcroMed, Inc., 669 A.2d 959, 969 (Pa. Super. 1995). Whether a warning is adequate depends on whether the learned intermediary, having considered “the data supplied to him by the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient,” would use his independent judgment to prescribe a medical device. Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1386 (Pa. 1991).

As noted above, Dr. Sotereanos testified that he did not read the package insert before implanting the hip replacement in Mr. Kline. In fact, Dr. Sotereanos never reads package inserts, which have warnings on them. Thus, even if the warning in this case were insufficient, it would not have made a difference. See Berry v. Wyeth, 2005 WL 1431742, at *5 (C.P. Phila. Cty. 2005) (when doctor testified that he never read the warning provided with a prescription drug, the plaintiff could not establish that any alleged failure to warn was the proximate cause of her injury). Other courts have come to the same conclusion: “We agree with the Second Circuit that a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician.” Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659, 661 (9th Cir. 2004) (citing Plummer v. Lederle Labs., Div. of Am. Cyanamid Co., 819 F.2d 349, 358-59 (2d Cir. 1987)). See also Porterfield v.

Ethicon, Inc., 183 F.3d 464, 468 (5th Cir. 1999) (when surgeon testified that he never read the warnings provided with the mesh, the plaintiff could not establish that alleged inadequate warnings were the cause of her injuries following hernia surgery); Appleby v. Glaxo Wellcome, Inc., 2005 WL 3440440, at *5-6 (D.N.J. Dec. 13, 2005) (same).

Dr. Sotereanos contends that he was aware of all of the warnings contained in the package insert (although he did not read it) based on the work he performed as a consultant for Zimmer during the design of this very device. There are several problems with this position. First, Dr. Sotereanos testified at his deposition that he was not aware that two warnings read to him were in the package insert. (Sotereanos Dep. at 62:5-63:3.) Second, there is at least some tension between Dr. Sotereanos's representation that Zimmer told him that the device was suitable for all patients regardless of body, habitus, BMI or activity level (Sotereanos Aff. ¶ 11), and the warning on the package insert that: "complications and/or failure of total hip prosthesis are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients who fail to follow through with the required rehabilitation program." Finally, the FDA requires that warnings be contained in the package insert of a medical device and, as explained above, Dr. Sotereanos cannot testify as to knowledge he gained about the device's uses, indications, contraindications, risks and warnings while working as a paid consultant for Zimmer because he is not an expert witness in this case. Plaintiffs point to no support for the contention that a defective warnings case can be based on information provided to a plaintiff's treating physician other than via the official warning on the package.

Plaintiffs contend that Zimmer should have warned surgeons about the dangers of implanting the device in patients above a certain weight or BMI and/or who engaged in a certain

level of activity. Defendants respond that this is not the proper standard to which device manufacturers are held in Pennsylvania and that Pennsylvania law does not require such specificity in a warning, particularly where, as here, the question is one of patient selection for a particular medical device. See, e.g., Salvio v. Amgen Inc., 2012 WL 517446, at *5-6 (W.D. Pa. Feb. 15, 2012) (rejecting plaintiff's negligent failure to warn claim, noting that a broad warning of a risk of infection was adequate and reasonable and that there was no need to include a more specific warning about fungal infections). See also Bergstresser v. Bristol-Myers Squibb Co., 2013 WL 6230489, at *7 (M.D. Pa. Dec. 2, 2013) ("The law does not require that the drug manufacturer provide such detailed information or instructions so as to remove the medical judgment of the physicians, who are in the best position to monitor and treat their patients and make medical judgments with respect to their care."); Aaron v. Wyeth, 2010 WL 653984, at *7-10 (W.D. Pa. Feb. 19, 2010) ("Under Pennsylvania law the determination whether a warning is adequate is a question of law," governed by a "reasonableness" standard.") (internal citations omitted)).

Plaintiffs argue that Dr. Sotereanos testified that, when he learned that two of his patients (one of whom was Mr. Kline) experienced fractures of the Kinectiv neck, he determined that he could no longer medically recommend the implant. In fact, he co-authored a study in which the subject was Mr. Kline's failed device and the authors concluded that they would recommend against routine use of this device unless absolutely necessary to achieve stability post-operatively. (Sotereanos Dep. at 46:25-47:4.)

Defendants respond that Plaintiffs appear to be relying on a "heeding presumption" argument; that is, they contend that, as a reasonable physician, Dr. Sotereanos would have heeded a different, adequate warning from Zimmer had it been provided. This argument fails,

however, because the “heeding presumption” has been applied only to strict liability causes of action, which are no longer part of this case. “Pennsylvania has never applied the heeding presumption to a negligence case.” Berry, 2005 WL 1431742, at *7.

In addition, the adequacy of a warning in prescription medical device cases generally must be proven by expert testimony. Demmler, 671 A.2d at 1154. Yet, Dr. Koss offered no opinion on Zimmer’s warnings and Ms. Truman conceded that Zimmer’s warnings were accurate and Defendants’ expert testified that they met and exceeded all industry standards. At most, Ms. Truman expressed a desire that the warnings could have been “more aggressive,” but this does not constitute evidence that they were inadequate. Thus, Plaintiffs have not shown that Zimmer’s warnings were inadequate, and their negligent warnings claim necessarily fails.

Because both of the negligence claims are unsupported as a matter of law, the motion for summary judgment should be granted with respect to Count I of the Complaint.

Loss of Consortium Claim

In Count V, Cherrie Kline alleges a loss of consortium claim derivative of Gregory Kline’s claims. Defendants move for summary judgment on the ground that, once Gregory Kline’s remaining claims are dismissed, Cherrie Kline can no longer be maintained. Defendants are correct. See Pusey v. Becton Dickinson & Co., 794 F. Supp. 2d 551, 565-66 (E.D. Pa. 2011). With respect to Count V, Defendants’ motion for summary judgment should be granted.

Motion in Limine

Defendants have also filed a motion in limine to exclude specific opinions of Plaintiffs’ expert witnesses and Plaintiffs have opposed the motion. Because the motion for summary judgment should be granted, it is not necessary to resolve this motion and it should be dismissed as moot.

For these reasons, it is recommended that the amended motion for summary judgment filed on behalf of the defendants (ECF No. 70) be granted. It is further recommended that the amended motion in limine to exclude specific opinions of plaintiffs' expert witnesses filed by the defendants (ECF No. 74) be dismissed as moot. It is further recommended that the motion to strike the affidavits of Mari Truman and Nicholas Sotereanos, M.D. filed on behalf of the defendants (ECF No. 84) be denied.

Litigants who seek to challenge this Report and Recommendation must seek review by the district judge by filing objections by March 13, 2015. Any party opposing the objections shall file a response by March 27, 2015. Failure to file timely objections will waive the right of appeal.

Respectfully submitted,

s/Robert C. Mitchell
ROBERT C. MITCHELL
United States Magistrate Judge

Dated: February 27, 2015